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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,146	02/01/2002	Roland Cherif Cheikh	0512-1009-1	1738

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EXAMINER	
BERKO, RETFORD O	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/060,146	CHEIKH, ROLAND CHERIF	
	Examiner	Art Unit	
	Retford Berko	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *73-94* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *73-94* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4/6/04* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Acknowledgement: *The Information Disclosure Statement filed February 2, 2002 and the Amendment filed January 30, 2004 are acknowledged.*

Status of Claims

Claims 1-72 were cancelled in view of applicant's preliminary Amendment.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 89 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term LHRH or analogue of LHRH is not readily understood or recognized to be the same chemical, compound or hormone by all persons of ordinary skill in the art. As used in the claim, the term "especially triptoreline" is indefinite as one cannot conclude whether it is the LHRH, its analogue or the triptoreline and/or its analogue that is implicated.

Applicant can overcome the rejection by providing the complete chemical name of the compound implicated as used by a person of ordinary skill in the field of endocrinology and also indicate the specific analogue of which compound that is being referred to in the claim.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

(a) Claims 73- 76, 80-82 and 86-89 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 18, 17, 14, 7-10 of U.S. Patent No. 6, 120, 786. This is a provisional obviousness-type double patenting rejection. Although the conflicting claims are not identical, they are not patentably distinct from each other because: (a) the scope of applicant's claims teach that the delayed release formulation is made of an active principle (b) the active principle can be a medicament, a drug, a protein, polypeptide, hormone or analogue of the hormone; with concentration of 40-100% (c) the excipients in the formulation can be a polylactic-glycolic copolymer (PLGA) (d) the formulation can be administered orally or parenterally in order to place the formulation into the body (e) the dimensions of the delayed release formulation range from 0.001 mm to 3.00 mm.

(b) The scope of claim 18 in Patent '786 teaches a slow release medicament in a polymer containing lactic acid or glycolic acid—the claim is broadly interpreted to mean that the formulation is contained in a polylactide-glycolide copolymer, which contains lactic acid and glycolic acid.

(c) Patent '786 teaches that the medicament dimensions range from 0.2 mm to 2.0 mm (see claims 7, 8, and 14). Patent '786 does not teach exact dimensions or amounts of active principle used in the medicament.

One of ordinary skill will be motivated to modify the parameters of the formulation, specifically such as the size of the medicament, the nature of the active principle, the amount of active principle as well as the amount of the carrier depending on the mode of action and individual patient needs in order to achieve effective delivery of the active principle, when such active principle is placed into the body (col 4, lin 25-45).

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 73, 74, 79, 80, 81, 82, 84, 86, 87, 89, 91 are rejected under 35 U.S.C. 102(b) as being anticipated by Kent et. al. (US 4, 675, 189). The claim is drawn to a delayed release formulation to be paced in the body containing polylactide-glycolide copolymer as excipient containing 40-100% active principle. The claims are also directed to the delayed release formulation wherein the copolymer of lactic acid and glycolic acid has a viscosity of greater than 0.6 dl/g.

5. Patent '189 teaches a sustained release formulation containing poly(lactide-glycolide) copolymer with active principle that can be hormones and their analogues in the amount of 40% wt/%, for parenteral administration (col 17, lin 45-50, col 18, lin 45-55). Patent '189 teaches that the polymer is 0.97 dl/g in chloroform.

6. These disclosures render the applicant's claimed invention anticipated.

Claims 73, 74, 79, 80, 81, 82, 84, 86, 87, 89, 91are anticipated by Kent et al (US 4, 675, 189).

Claim Rejections-35 USC Sec. 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The relevant part of the factual inquiries set forth in Graham v. John Deere & Co., 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and content of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue
3. Resolving the level of ordinary skill in the pertinent art
4. Considering objective evidence present in the application indicating obviousness or non-obviousness.

9. Claims 75-78, 83, 85, 87, 88 and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kent et al (US 4, 675, 189) in view of Orsolini et al (US 5, 445, 832). Applicant's claims are drawn to a slow release formulation wherein the active ingredient is carried in an excipeint made of polylactic-glycolic copolymer with specified dimension of the medicament in the slow release formulation, the rate of release, amounts of active ingredients in the formulation and the routes of administration.

10. Kent et al (Patent '189) discloses a slow release formulation containing pharmaceutically acceptable active ingredient (40%) that is a hormone analog, with polylacide-polyglycolide copolymer as excipients and can be administered parenterally (col 17 and col 18, lin 40-55). Patent '189 does not teach specific dimensions of the medicament.

11. Orsolini et al (Patent '832) teach sustained release formulation wherein the excipeint is a copolymer of lactic acid and glycolic acid copolymer (col 3, lin 20, col 4, lin 60col 5, lin 15-20 and col 13, lin 30-65). Patent '832 further teaches that the dimension of the medicament can be in microns (col 5, lin 15), that the amount of active ingredient in the formulation can be 5, 10, 20% or even higher and can be administered parenterally (col 4, lin 25-40).

12. One of ordinary skill in the art would be motivated to use different sizes and amounts of medicament in order to obtain effective desired doses delivered to patients during therapy of sustained release delivery of medicament. The person making the device has control over the parameters such as size of the delivery device. Thus absent any showing of criticality, merely altering such parameters such as size do not constitute an inventive step. Therefore, the invention as a whole would have been prima facie obvious at the time of the invention.

13. Claims 91-94 are rejected under 35 U.S.C. 103(a) as being unpatentable in view of Kent et al (US 4, 675, 189) in vie w of Orsolini et al (US 5, 445, 832) further in view of Boyan et al (US 5, 492, 697).

14. The scope of claims 91-94 is directed to a process of preparing a sustained release formulation entailing producing a homogeneous mixture of excipients and active principle in proportions, compression, grinding and administering in suitable form. According to the claims, the excipeint is a copolymer of lactidie-polylactide copolymer.

15. Patent '189 and Patent '832 disclose a composition that is a sustained release formulation wherein the excipeint is polylactide-glycolide copolymer with active ingredient. Patent '189 teaches a process of making the formulation wherein emulsification is used for preparing the polylactide-glycolide copolymer containg the active agent. The method also

entails stiring the polymeric excipients and precipitation yielding microcapsules (col 13, lin 55 continuing to col 14, lin 5).

16. Patent '697 discloses a method of making a sustained release implant containing polyalctide-glycolic copolymer as excipeint with active ingredient—hormones, enzymes, drugs etc. (col 16, lin 30 and col 24, lin 40-60; --the method includes solubilization of polymer in a in a suitable liquid, gelling, molding, precipitation; yielding the desired implant containing the active agent suitable solution, gelling, molding and precipitation in order to obtain the desired implant containing the active agent in a suitable solution, gelling, molding and precipitation in order to obtain the desired implant containing the active agent.

17. One of ordinary skill in the art would be motivated to use different method and amounts of active agents in order to obtain the same effective formulation containing polylactide-glycolide and active agent for delivery to patients having individual needs during therapy with sustained release delivery of medicament. Therefore, the invention as a whole would have been prima facie obvious at the time of the invention.

18. One of ordinary skill in the art would be motivated to use different method and amounts of active agents in order to obtain the same effective formulation containing polylactide-glycolide and active agent for delivery to patients during therapy of sustained release delivery of medicament. One of ordinary skill in the art would be motivated to prepare delayed release microcapsules comprising an active agent by the methods disclosed in Patent '189 and Patent 832. By combining with methods disclosed in Patent '697, one of ordinary skill would expect to obtain the same controlled release drug delivery device having different sizes and amounts of

medicament in order to deliver to individual patients having different needs. Therefore, the invention as a whole would have been prima facie obvious at the time of the invention.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Retford Berko** whose telephone number is571-272-0590. The examiner can normally be reached on M-F from 8.00 am to 5.30 pm

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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